FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY MINUTES OF AD HOC COMMITTEE ON GUIDANCE FOR SUGGESTED DISCIPLINARY ACTION RESULTING FROM ROUTINE INSPECTIONS OF PHARMACIES AND PHYSICIANS LICENSED TO DISPENSE

November 25, 2013

Second Floor Board Room 2

Perimeter Center 9960 Mayland Drive Henrico, Virginia 23233-1463

CALL TO ORDER:

The meeting was called to order at 11:10AM.

PRESIDING:

Ellen Shinaberry, Committee Chairman

MEMBERS PRESENT:

R. Crady Adams Jody Allen Empsy Munden Cynthia Warriner

Rebecca Thornbury (left at 2:30pm)

STAFF PRESENT:

Caroline D. Juran, Executive Director

J. Samuel Johnson, Jr., Deputy Executive Director Cathy M. Reiniers-Day, Deputy Executive Director

APPROVAL OF AGENDA:

With no changes made to the agenda, the agenda was approved as

presented. (motion by Warriner, second by Adams)

DISCUSSION:

Ms. Juran provided an overview of the agenda packet and feedback she has informally received regarding the process used for disciplinary action following a routine pharmacy inspection. While many pharmacists have indicated they appreciate the transparency which Guidance Document 110-9 provides, some independent pharmacy owners have indicated they do not like the issuance of a public document against the pharmacy permit when a monetary penalty is imposed. Prior to beginning its discussions, the committee received public comment from Ron Davis, President of the Virginia Pharmacists Association (VPhA). He indicated that VPhA is not happy with the routine pharmacy inspection process and that it has decayed the relationship between VPhA and the Board. He stated the Board should deal with major offensives, but not impose monetary penalties for minor offensives. He encouraged voluntary compliance with minor offensives. He supported the idea of sanctioning for repeat violations.

The committee also received comment from Tim Musselman, Executive Director of the Virginia Pharmacists Association (VPhA). He indicated VPhA supports all dispensers being held to the same standard. He stated one of the biggest concerns with the inspection process is the public record against the pharmacy permit which results when monetary penalties are imposed. He recommended the Board focus on the immediate impact on public health when considering disciplinary action for specific deficiencies; he provided a handout with suggested amendments to Guidance Document 110-9 (Attachment 1).

The committee discussed each major and minor deficiency within Guidance Document 110-9, taking into consideration how often it has been cited in the past and the suggested changes provided by VPhA. The committee offered suggestions for amending certain deficiencies and thresholds, which determine when deficiencies will be cited. Additionally, it discussed increasing the number of minor deficiencies that must be cited prior to imposing a monetary penalty. The committee discussed possible disciplinary action which could be imposed on a pharmacy that is cited the same deficiency in subsequent inspections. The committee recommended no action on this issue at this time. Ms. Juran indicated she was aware that representatives associated with free clinic pharmacies wish the Board to consider reducing monetary penalties imposed against these pharmacies following a routine pharmacy inspection. She reported that a legislator had also recently called staff expressing concern for a monetary penalty imposed against a free clinic pharmacy. The committee recommended no action on this issue at this time, but expressed a desire to hear more on this subject at the December full board meeting. The committee concluded it will recommend to the full Board to implement a similar process for handling deficiencies cited during routine inspections of physicians licensed to dispense drugs. Time did not permit the committee to begin drafting a guidance document similar to 110-9. The committee expressed desire to reconvene prior to the March 2014 full board meeting for the purpose of drafting guidance which would identify specific deficiencies and associated monetary penalties to be imposed following a routine inspection of physicians licensed to dispense.

MOTION:

The Committee voted unanimously to recommend the following to the full board for its consideration:

- amendments to Guidance Document 110-9 as indicated in Attachment 2; and,
- implementation of a similar process for handling disciplinary action resulted from deficiencies cited during routine inspections of physicians licensed to dispense drugs; that the pre-hearing consent order be issued against the individual licensed to dispense or the responsible designated practitioner, when a common stock of drug is maintained; and, reconvene, prior to the March 2014 full board meeting, the ad hoc committee to develop guidance similar to Guidance Document 110-9 to identify deficiencies and suggested monetary penalties. (motion by Warriner, second by Allen, Thornbury absent for vote)

ADJOURN:	With all business concluded, the meeting adjourned at 4:50PM.
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Ellen Shinaberry, Committee Chairman	Caroline D. Juran, Executive Director
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Date	Date